

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ROBERT ZEMAN AND JULIA ZEMAN,

Plaintiffs,

v.

ZIV WILLIAMS, M.D., EMAD ESKANDAR, M.D.,
INDIVIDUAL MEMBERS OF THE
INSTITUTIONAL REVIEW BOARD: MELISSA
FRUMIN, M.D., HINA ALAM, SARY F. ARANKI,
M.D., RHONDA BENTLEY-LEWIS, M.D., SUSAN
BURNSIDE, RICHARD D'AUGUSTA, ASHWIN
DHARMADHIKARI, M.D., DAVID A. JONES,
M.D., DEBORAH ECKER, ROBERT J. GLYNN,
ELIZABETH L. HOHMANN, M.D., THOMAS
KOLOKOTRONES, KEITH A. MARCOTTE,
FRANCISCO MARTY, M.D., ELINOR A. MODY,
M.D., JOAN RILEY, ANDREW P. SELWYN,
ARTHUR C. WALTMAN, M.D., SJIRK WESTRA,
M.D. AND SEAN R. WILSON, M.D.,
MEDTRONIC, INC., AND NEUROLOGIX, INC.,

Defendants.

Case No. 1:11-CV-10204-MLW

MEMORANDUM IN SUPPORT OF NEUROLOGIX, INC.'S
MOTION TO DISMISS

INTRODUCTION

This motion to dismiss presents the unique issue of whether a patient in an FDA-approved clinical drug trial can sue the trial sponsor when an unexpected event occurs in violation of the sponsor's study protocol. Accepting as true the alleged facts presented by this plaintiff, the answer must be "no."

Plaintiff Robert Zeman suffers from an advanced case of Parkinson's disease—a progressive and debilitating neurodegenerative disorder for which there is no cure. Defendant Neurologix, Inc. ("Neurologix") invented an experimental gene therapy drug as a treatment option for those suffering from this horrible disease. Exploring every available treatment option, Mr. Zeman traveled across the country to Massachusetts General Hospital to become a patient in an FDA-approved clinical study sponsored by Neurologix. After consultation with his treating physician, including acknowledgment of a 22-page informed consent document, Mr. Zeman agreed to enter the trial and undergo a standard surgical procedure used in treating patients with Parkinson's disease that would insert catheters in each side of his brain to allow infusion of the gene therapy drug.

Unfortunately, instead of occurring in the manner prescribed by Neurologix's FDA-approved study protocol, Mr. Zeman's surgeon gave him a "double dose" of the gene therapy drug in one side of Mr. Zeman's brain by placing *both* the left- and right-side catheters in the left side of his brain. Although Mr. Zeman unequivocally alleges that his injuries were the result of this surgical mistake, and he brings multiple counts of malpractice against the defendant

physicians leading the study, he nonetheless adds additional counts sounding in negligence and breach of warranty against Neurologix, the clinical trial sponsor.¹

As a matter of law, clinical trial sponsors like Neurologix owe no direct duties of care to patients like Mr. Zeman participating in an FDA-approved clinical study because the care of the patient lies with his treating physician. As a matter of fact, Mr. Zeman's Amended Complaint does not contain a single allegation that Neurologix actually breached any supposed duty, and indeed confirms that any conduct by Neurologix could not be the cause of his alleged injuries. Therefore, the Court should grant Neurologix's motion to dismiss.

FACTUAL BACKGROUND²

Mr. Zeman suffers from Parkinson's disease. Amended Complaint at ¶15. In 2008, Mr. Zeman elected to participate in a clinical trial titled, "Safety and Efficacy Study Evaluating Glutamic Acid Decarboxylase Gene Transfer of Subthalamic Nuclei in Subjects with Advanced Parkinson's Disease." *Id.* at ¶21, 36. The understood purpose of the study was to determine the safety and effectiveness of this innovative type of treatment for Parkinson's. *Id.* at Ex. A, p.1. Neurologix was the sponsor of the clinical trial. *Id.* at ¶25.

¹ On April 20, 2011, over two months after filing his initial complaint, Mr. Zeman filed an Amended Complaint which adds the individual members of the Mass General Institutional Review Board as additional defendants. The Amended Complaint contains no additional allegations with respect to Neurologix, but now serves as the operative pleading.

² Although Neurologix disputes many of the allegations contained in the Amended Complaint, Neurologix accepts the allegations as true for purposes of this motion to dismiss. Indeed, participants who received Neurologix's investigational drug experienced statistically significant and clinically meaningful improvements in off-medication motor scores as compared to control subjects who did not receive the drug. *See, e.g., AAV-GAD gene therapy for advanced Parkinson's disease: a double-blind, sham-surgery controlled, randomized trial, The Lancet Neurology*, Vol. 10, Iss. 4, p. 309-19 (Apr. 2011). Under the factual scenario portrayed in Mr. Zeman's complaint, it is clear that even if Mr. Zeman suffered the injuries he alleges (a fact Neurologix very much disputes), the alleged injuries had nothing to do with Neurologix's investigational drug or the protocol. The Court should be mindful that allowing Zeman's pending claims against Neurologix and Medtronic would hinder a clinical study that offers a potential breakthrough in the treatment of Parkinson's disease.

Under the terms of the trial, Mr. Zeman was to receive an infusion of the study drug containing certain genes directly into both sides of his brain in an effort to produce an enzyme called Glutamic Acid Decarboxylase. Amended Complaint at ¶21. The presence of this enzyme would cause an increased production of gamma-aminobutyric acid, a neurotransmitter in short supply in the brains of individuals suffering from Parkinson's. *Id.* To supply the gene therapy directly to the brain, the study required a delivery device that could connect to the patient's brain. For this purpose, defendant Medtronic, Inc. ("Medtronic") developed the Acute Brain Infusion Delivery System ("ABID System"), which is comprised of catheters that introduce the study agent into the brain, a small cap to cover the hole in the skull during the procedure, and a pump with a syringe on it. *Id.* at ¶25; Ex. A, p.6. The medical professionals conducting the study utilized the ABID System to deliver the genes directly into the two sides of the brain. *Id.* at ¶25.

Mr. Zeman, a California resident, elected to travel to Boston to participate in the clinical study at Massachusetts General Hospital ("Mass General"). Amended Complaint at ¶19. The Principal Investigator who oversaw the study at Mass General was Defendant Dr. Emad Eskandar. *Id.* at ¶22, Ex. A, p.1. On November 17, 2008, a few weeks in advance of the scheduled procedure, Dr. Eskandar (not Neurologix or Medtronic) met with Mr. Zeman to discuss the contents of Mass General's Research Consent Form ("Informed Consent"). *Id.* at ¶31.

The 22-page Informed Consent (attached as Exhibit A to the Amended Complaint) explained the risks associated with the clinical study, including that:

- "At present, human gene transfer is experimental." (p.2)
- "The study agent is experimental. Not all risks or side effects are known. Some side effects may be life threatening." (p.2)
- The ABID System "is experimental and has NOT been approved by the FDA. It is being developed as a device for delivery of drugs in brain tissues." (p.6)

- “The Medtronic Acute Brain Infusion Delivery System used to infuse the study agent has not been approved by the FDA and is considered experimental.” (p.11)
- “To summarize, the surgical risks associated with brain surgery may include: Paralysis, coma, and/or death . . . Bleeding inside the brain (stroke) [and] . . . Temporary or permanent neurological complications.” (p.11-12)
- The ABID System “is experimental. It may have risks that are unknown.” (p.12)

Mr. Zeman signed the Informed Consent, agreeing specifically that he (a) had “read this consent form,” (b) “had the opportunity to ask questions,” and (c) had the research study “explained to [him], including risks and possible benefits (if any), other options for treatments or procedures, and other important things about the study.” Amended Complaint at Ex. A, p.20-21.

On December 4, 2008, Mr. Zeman underwent the gene therapy procedure. Amended Complaint at ¶36. Defendant Dr. Ziv Williams (a colleague of Dr. Eskander) performed the procedure at Mass General. *Id.* at ¶37. According to Mr. Zeman’s complaint, “[r]ather than placing the catheter in the ABID System into each side of Plaintiff Zeman’s brain, in accordance with the experiment’s design and the [Informed Consent’s] warnings,” Dr. Williams placed both catheters in the left side of the brain. *Id.* at ¶38 (emphasis added). Mr. Zeman also alleges that shortly after the surgery, Mass General performed a CT scan, which confirmed that the right catheter had been mistakenly placed in the left side of Mr. Zeman’s brain. *Id.* at ¶39 & Ex. B. He thus specifically alleges that Dr. Williams “fail[ed] to use the ABID System properly.” *Id.* at ¶70j.

According to Mr. Zeman, two weeks after the surgery Dr. Williams told him that he only received the study agent on one side, the left, because there was a “‘kink’ in the right side catheter.” Amended Complaint at ¶42. But Mr. Zeman later alleges that Dr. Williams “lied” about the existence of this kink in the ABID System. *Id.* at ¶88a. Indeed, months later, Dr.

Williams told Mr. Zeman that “their best estimate was that he did not receive a double dose because they believed the right catheter had malfunctioned.” *Id.* at ¶55. Quite to the contrary, “[n]othing in the medical records provided to Plaintiff Zeman corroborates the claim that the right catheter malfunctioned.” *Id.* (emphasis added). Instead, the Mass General CT scan confirms the undisputed fact that lies at the center of this litigation; namely, “that the right side catheter had mistakenly terminated in the left sub-thalamic nucleus where the left catheter had been placed.” *Id.* at ¶57 (emphasis added). *See also id.* at Ex. B (“Right trans-frontal deep brain stimulator electrode traverses midline and terminates within the left subthalamic region.”).

Mr. Zeman now alleges that, “[a]s a result of the infusion of a double dose of the study agent on only one side of the brain,” he has suffered and will continue to suffer severe and debilitating injuries. Amended Complaint at ¶62. Nowhere in his complaint does Mr. Zeman allege that Neurologix in any way designed its study protocol for a surgeon to administer a double dose of the study agent on only one side of a patient’s brain.

STANDARD OF REVIEW

Under the so-called “Twombly-Iqbal” standard, to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must contain sufficient factual matter to state a claim to relief that is plausible on its face. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 44 (1st Cir. 2008). When considering a motion to dismiss, a court may consider not only the factual allegations stated within the complaint, but also the facts set forth in any attached exhibits (such as the ones proffered by Mr. Zeman). Fed. R. Civ. P. 10(c). Although a court must accept as true all of the factual allegations contained in a complaint, a court need not accept as true legal conclusions or naked assertions devoid of further factual enhancement. *Ashcroft v. Iqbal*, 129 S. Ct. 1938, 1949 (2009).

Threadbare recitals of the legal elements, supported by mere conclusory statements, do not suffice to state a cause of action. *Id.*; see also *DM Research v. College of Am. Pathologists*, 170 F.3d 53, 55-56 (1st Cir. 1999) (while plaintiff's facts are accepted as true, bald assertions and legal conclusions are not). A complaint does not state a claim for relief where the well-pled facts fail to warrant an inference of any more than the mere possibility of misconduct. *Iqbal*, 129 S. Ct. at 1950. Most relevant to this action, a court "is not obligated by the standard of review to disregard factual allegations that undermine a plaintiff's claim." *Pugel v. Bd. Of Trustees of Univ. of Ill.*, 378 F.3d 659, 665 (7th Cir. 2004).

ARGUMENT

The plain language in Mr. Zeman's Amended Complaint establishes that he has failed to allege any claim against Neurologix that can survive Rule 12(b)(6) scrutiny. After he meticulously outlines ten substantive counts against his treating surgeon and the surgeon's hospital supervisors, Mr. Zeman tacks on three more against the drug manufacturer Neurologix—a negligence claim for failing to warn him of the dangers of the clinical study (Count XI), and negligence/breach of implied warranty claims sounding in product liability (Counts XII and XIII).³

For the reasons set forth in detail below, the Court should grant Neurologix's motion to dismiss all claims against it. Count XI fails both because (a) Neurologix does not owe any direct legal duty to Mr. Zeman, and (b) even if this Court were to create such duty, the facts as alleged by Mr. Zeman do not support the claim that Neurologix caused Mr. Zeman's injuries. Count XII fails for three reasons: (a) the claim is preempted by federal law; (b) the facts as alleged

³ Mr. Zeman's wife also brings a Loss of Consortium claim against all defendants (Count XIV), which fails against Neurologix due to the lack of a surviving underlying tort.

specifically contradict any claim of product defect; and (c) even if this Court were to ignore the alleged facts and assume the product was somehow defective, the surgical error, not the drug, was the cause of any alleged injuries. Count XIII fails for similar reasons—as a matter of law, the alleged facts simply do not support a finding of liability.

I. Count XI – As Both a Matter of Law and Under His Alleged Facts, Mr. Zeman Cannot Prove Negligence by Neurologix for Failure to Warn.

Mr. Zeman alleges that Neurologix was negligent in failing to warn him of the dangers of its clinical study. Specifically, Mr. Zeman contends that Neurologix, as study sponsor, is liable because it breached a duty to draft and approve the Informed Consent “with due care for the safety of experimental subjects such as Zeman.” Amended Complaint at ¶134. This claim is not only in direct conflict with black-letter law, but contrary to the factual allegations of Mr. Zeman’s own complaint.

To prevail on his negligence claim, Mr. Zeman must prove (1) that Neurologix owed Mr. Zeman a duty of reasonable care, (2) that Neurologix breached this duty, (3) that damage resulted to Mr. Zeman, and (4) that there was a causal relation between the breach of the duty and the damage. *Jupin v. Kask*, 447 Mass. 141, 146 (2006); *see Smith v. Jenkins*, 718 F. Supp.2d 155, 168 (D. Mass. 2010). Mr. Zeman’s claim fails on all four elements.

A. It is black letter law that a clinical study’s investigators, and not its sponsor, owe the legal duty to warn a patient of risks and to obtain an informed consent.

It is axiomatic that in order to prevail on a negligence claim, a plaintiff must first establish that the defendant owed plaintiff a legally cognizable duty. *Afarian v. Massachusetts El. Co.*, 449 Mass. 257, 261 (2007). Whether defendant owes plaintiff a duty is a question of law, and thus is easily susceptible to resolution at this stage. *Id.*; *Brown v. U.S.*, 557 F.3d 1, 3 (1st Cir. 2009).

Here, Mr. Zeman acknowledges that Neurologix served as the sponsor of the clinical study, and that doctors at Mass General (Drs. Eskandar and Flaherty) served as the investigators.

The law is clear that only the investigators in a clinical study owe a patient duties to warn of the risks of participating in the study and to obtain an informed consent. *See Darke v.*

Estate of Isner, 2005 WL 3729113 (Mass. Super. Ct. Nov. 22, 2005). *See also Suthers v. Amgen, Inc.*, 441 F. Supp.2d 478 (S.D.N.Y. 2006) (rejecting negligence and fiduciary duty claims against a sponsor of clinical trial because the sponsor did not owe a duty to plaintiff); *Kernke v. The Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117 (D. Kan. 2001).

The federal regulations covering clinical studies explicitly limit to investigators the responsibilities for “protecting the rights, safety, and welfare of subjects under the investigator’s care,” *see* 21 C.F.R. § 312.60,⁴ and for obtaining an informed consent, *see* 21 C.F.R. § 50.20.⁵ Multiple jurisdictions have applied these regulations to foreclose clinical study patients from claiming that the study sponsor owes a duty to inform of risks.

For example, in *Kernke*, the United States District Court of Kansas addressed facts strikingly similar to this case and found that a clinical study sponsor could not be liable in negligence to the trial participant because there was no duty running from the sponsor. Defendant Aventis had sponsored a clinical study to test the safety and efficacy of its new investigational drug for schizophrenia. *Kernke*, 173 F. Supp. 2d at 1119. The Menninger Clinic and its doctors served as study investigators. *Id.* Plaintiff Kernke participated in the study after

⁴ “An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator’s care; and for the control of drugs under investigation. An investigator shall, in accordance with the provisions of part 50 of this chapter, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 50.23 or 50.24 of this chapter.” 21 C.F.R. § 312.60.

⁵ “Except as provided in 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.” 21 C.F.R. § 50.20.

signing a consent form provided and explained by the Menninger Clinic. *Id.* at 1120. A few months into the study, Kernke was found dead of exposure in a wooded area near the Menninger Clinic. *Id.* Kernke's family brought suit against the Menninger Clinic and its doctors. *Id.* The family also brought suit against Aventis for negligence based on three separate duties: (1) to determine that the benefits of Kernke participating in the study outweighed the risks, (2) to secure the informed consent from Kernke, and (3) to supervise Kernke while he participated in the study. *Id.* at 1118-19, 1124. The court rejected each argument, holding that Aventis, as study sponsor, owed none of these duties to Kernke:

Pursuant to the directive of the United States Congress in the Federal Food, Drug and Cosmetic Act, a study involving the use of an investigational drug such as M100907 is governed by regulations issued by the FDA. According to the FDA regulations, an investigator—in this case the Menninger defendants—is defined as “an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject).” On the other hand, a sponsor—in this case Aventis—“does not actually conduct the investigation unless the sponsor is a sponsor-investigator.” All of the duties alleged by plaintiffs in this case fall within the purview of the Menninger defendants as the investigator conducting the M100907 study; the duties do not rest with Aventis. *Id.* at 1124 (internal citations omitted).

Because Aventis did not owe Kernke a direct legal duty, the court found in favor of Aventis on plaintiff's negligence claim as a matter of law.

Pursuant to the same reasoning, in *Darke* the Massachusetts Superior Court found that a sponsor of a clinical trial was free from liability in negligence because, as a matter of law, it did not owe plaintiff a duty. 2005 WL 3729113, at *14-15. There the plaintiff brought a negligence claim against Vascular Genetics, Inc., the trial sponsor. *Id.* at *2-3. The court referenced applicable FDA regulations, holding that the investigator is responsible for “protecting the rights, safety, and welfare of the subjects under the investigator's care, and obtaining the informed consent of each human subject to whom the drug is administered.” *Id.* at *15 (citing 21 C.F.R. §

312.60). Since these responsibilities fell only to the investigator, Vascular Genetics “did not directly owe specific duties” to Darke, and thus there was no action for negligence. *Id.* at *15.

Similarly, Mr. Zeman cannot pursue a negligence action against Neurologix based on the Informed Consent. Mr. Zeman specifically alleges that Neurologix’s role in the clinical study was that of sponsor only. Amended Complaint at ¶132. Mr. Zeman also alleges that “originally Defendant Dr. Eskandar and later a Dr. Alice Flaherty” served as principal investigators. *Id.* at ¶22. It is for this reason that Mr. Zeman alleges an almost identical negligence claim against Dr. Eskandar in his role as principal investigator rooted in a duty to exercise “due care for the safety of experimental subjects such as Plaintiff Zeman.” *Id.* at ¶109.⁶

Strong public policy reasons support shielding sponsors from any duty involving the informed consent. It is the investigators with whom the participant expects to discuss the risks and dangers of the clinical study. After all, the doctor-patient relationship facilitates the free flow of necessary information between investigator and participant. This relationship does not exist between a participant and the study sponsor—particularly in a clinical study such as this one where a subject’s identity is blinded to the sponsor. To superimpose a duty on the sponsor would create a scenario in which sponsors may feel compelled to involve themselves in, and perhaps override, the sacrosanct doctor-patient relationship.

Because Neurologix did not owe Mr. Zeman a legal duty of care with respect to the Informed Consent, Count XI must be dismissed.

⁶ It was Dr. Eskandar who signed the Informed Consent on behalf of the study. Moreover, the Informed Consent, attached as Exhibit A to the Amended Complaint: (1) is labeled as a PartnersHealthCare System document, Ex. A at 1; (2) states that “Emad Eskandar, MD is the person in charge of this study. You can call him at . . . any time,” Ex. A at 17; and (3) lists Dr. Eskandar as the one who “explained the research to the study subject” and “answered all questions about this research study to the best of my ability.” Ex. A at 22.

B. Even if Neurologix did owe a duty with respect to the informed consent, any breach—whatever that unidentified breach could possibly be—was not the cause of Mr. Zeman’s alleged injuries.

Even if this Court were to assume that Neurologix did owe a legal duty to Mr. Zeman, and that Neurologix somehow breached that duty by failing to offer Mr. Zeman adequate warnings, Mr. Zeman’s claim still does not pass muster.⁷ As explained more fully *infra*, in Section II.B, Mr. Zeman’s injuries were not the result of any breach committed by Neurologix. Instead, the Amended Complaint plainly alleges that Mr. Zeman’s injuries were caused by a surgical error that delivered the investigational drug twice in the same side of his brain. Amended Complaint at ¶62. This was contrary to the design of the Neurologix trial protocol, *id.* at ¶21, and Neurologix should not be held responsible for this unexpected surgical result. *See Kent v. Commonwealth*, 437 Mass. 312 (2002).

II. Count XII – Under Well-Settled Law and the Alleged Facts, Mr. Zeman Cannot Prevail on His Claim of Products Liability Negligence.

To prevail on a products liability negligence claim, a plaintiff must prove not only that the defendant manufactured a legally defective product that caused the defendant’s injury, but also that the defendant failed to exercise reasonable care to avoid foreseeable risks that the product could cause harm. *Laspesa v. Arrow Int’l, Inc.*, 2009 WL 5217030 (D. Mass. Dec. 23, 2009). Again, Mr. Zeman cannot meet these requirements in law or in fact.

A. Mr. Zeman’s product liability claim is preempted by federal law.

Mr. Zeman bases his products liability negligence claim solely on allegations that Neurologix and Medtronic manufactured the ABID System “in violation of the Federal Food, Drug and Cosmetic Act (‘Act’) and regulations promulgated pursuant to said Act,” Amended

⁷ Neurologix strongly disputes that Mr. Zeman was uninformed with respect to the risks in participating in the study. The Informed Consent attached to the Amended Complaint is thorough, and Mr. Zeman was a capable and educated patient who knowingly agreed to experimental surgery, well aware of the possibility of surgical error.

Complaint at ¶142, and “in violation of the terms, conditions, standards and specifications of the Investigational Device Exemption (‘IDE’) secured by Satiety [sic] from the Food and Drug Administration’s Premarket Approval Process (‘PMA’).” *Id.* at ¶143.⁸ In so doing, Mr. Zeman unsuccessfully attempts to circumvent FDA preemption by bringing a so-called “parallel” claim.

A parallel claim requires an allegation of violation of FDA regulations or requirements relating to the device, and a causal nexus between the alleged injury and violation. *Cohen v. Guidant Corp.*, 2011 WL 637472, at *1 (C.D. Cal. Feb. 15, 2011). A bare bones legal conclusion is insufficient to make out a claim for violation of FDA regulations. *See Aschroft v. Iqbal*, 129 S.Ct. at 1950 (a pleading that merely recites bare legal conclusions is insufficient to “unlock the doors of discovery”). Mr. Zeman’s product liability claim is just that—a conclusory allegation with no supporting facts. Mr. Zeman does not allege which FDA regulations or terms, conditions, standards, and specifications of the protocol that Neurologix and Medtronic purportedly violated, let alone offer any factual support to show a violation. “Plaintiffs cannot simply incant the magic words ‘[defendant] violated FDA regulations’ in order to avoid preemption.” *In re Medtronic*, 592 F.Supp.2d 1147, 1158 (D. Minn. 2009). *See also Cohen*, 2011 WL 637472, at *1 (“Absent factual support and details, general allegations that Defendants failed to comply with federal requirements are inadequate to plead parallel claims . . .”); *Gelber v. Stryker Corp.*, 752 F.Supp. 2d 328, 334 (S.D.N.Y. 2010) (dismissing complaint because it did not allege “device-specific violations of federal law” or “how those violations have a cognizable

⁸ It is likely that Mr. Zeman meant to allege that either Neurologix or Medtronic secured FDA approval. Neurologix is not aware of how Satiety, Inc. would be relevant to this action. Interestingly, in the recent decision *Burgos v. Satiety*, 2010 WL 4907764 (E.D.N.Y. Nov. 30, 2010), the court found against the plaintiff on state law claims sounding in negligence, breach of warranty, and strict liability, holding that each was preempted by FDA regulations. “Because IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices, the body of preemption law governing PMA devices applies equally to the IDE device at issue in this case.” *Id.* at *2.

link to [plaintiff's] injuries"); *Burgos*, 2010 WL 4907764, at *3-4 (finding mere claim of a violation of "statutes, codes, laws, ordinances, rules and regulations" insufficient to make out a parallel claim); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *6 (D. N.J. Mar. 5, 2009) (dismissing parallel claim that amounted to nothing more than a "bald allegation" of a manufacturing defect). As a result, Mr. Zeman has not set forth a plausible claim that Medtronic and Neurologix manufactured the ABID System in violation of federal regulations. *Gelber*, 752 F.Supp. 2d at 334 ("Twombly clearly requires more than a conclusory statement that Defendants violated federal code and rule."); *In re Medtronic*, 2009 WL 294353, at *3 (D. Minn. Feb. 5, 2009) (rejecting plaintiff's attempt at "Court-sanctioned roulette," because "[i]t is simply not enough for Plaintiffs to baldly allege that Medtronic violated federal law in order to obtain discovery").

Neurologix and Medtronic underwent extensive FDA review to secure the approvals necessary for the clinical trial. Mr. Zeman has not alleged any specific violation of these approvals. Were the Court now to allow Mr. Zeman to pursue state law tort claims against Neurologix and Medtronic based on the very study and device permitted for use by the FDA, it would impermissibly infringe upon the FDA's regulatory authority over clinical studies, whose very purpose is to test the safety of developing medicine. If this Court sanctioned Mr. Zeman's theory of liability here, it would render it "impossible for a private party to comply with both state and federal law" and would create "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citation omitted). See *Geier v. American Honda Motor Co.*, 529 U.S. 861, 871 (2000) ("[T]oo many safety-standard cooks" lead to "conflict, uncertainty, cost, and occasional risk to safety . . ."). Allowing lay jurors to augment the already stringent

requirements of federal law for the use of medical devices in clinical studies would undermine Congress's express objective of charging FDA with the responsibility for calibrating these matters. As the First Circuit observed in an analogous context, "[i]f their legal risks [are] too great, worthwhile medical devices may be left in the laboratory, to the public's loss." *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir. 1993).

B. Mr. Zeman's complaint admits there was no defect.

Even more telling, although Mr. Zeman's claim for products liability negligence is premised on his unsupported legal conclusion that "Defendants Medtronic and Neurologix negligently manufactured and/or designed the ABID System," Amended Complaint at ¶144, ***Mr. Zeman alleges no facts explaining how the ABID System was defective.*** To survive Rule 12(b)(6) scrutiny, a plaintiff must allege more than a bald assertion that the device was defective. *Maness v. Boston Scientific*, 751 F.Supp.2d 962, 970 (E.D. Tenn. 2010) (dismissing products liability claim because plaintiff failed to allege facts demonstrating why the device was defective or unreasonably dangerous); *Steen v. Medtronic, Inc.*, 2010 WL 2573455, at *2 (N.D. Tex. June 25, 2010) (dismissing products liability claim where plaintiff alleged a defect but failed to allege how the device was defective). In fact, to the contrary, Mr. Zeman admits that the ABID System did not malfunction, but rather that a defendant surgeon erred by inserting both catheters in the same side of his brain, and then "lied" about a failure in the ABID System. *Id.* at ¶¶38, 88a. According to the Amended Complaint, the only mention of there being a "kink" in the ABID System was an initial misstatement by the surgeon who performed Mr. Zeman's operation. Specifically, Mr. Zeman alleges that:

Approximately two weeks after the surgery, Plaintiff Zeman met with Defendant Dr. Williams who "unblinded" him and told him he had received the study agent. Defendant Dr. Williams advised, however, that said plaintiff only received the study agent on one side, the left, because there was "a kink" in the right side catheter. The doctor advised they did not know where the catheter ended up on

the right side but that it most likely did not end up in the sub-thalamic region of the brain, though he advised there was a small chance of the genes going into the right side subthalamic nucleus where they were supposed to go. ***This was not true.*** *Id.* at ¶42 (emphasis added).

Significantly, Mr. Zeman later alleges that ***“Nothing in the medical records provided to Plaintiff Zeman corroborates the claim that the right catheter malfunctioned.”*** *Id.* at ¶55 (emphasis added). Where the Amended Complaint unequivocally alleges that there was no defect in the ABID System, Mr. Zeman cannot prove that Neurologix or Medtronic negligently manufactured or designed the ABID System. *See Brown v. Husky Injection Molding Sys., Inc.*, 751 F.Supp.2d 298 (D. Mass. 2010) (finding for defendant on products liability claim where plaintiff offered no evidence that a defect existed when the product left defendant’s hands). Mr. Zeman has fallen far short of alleging sufficient facts to state a claim for relief that is plausible on its face. *See Twombly*, 550 U.S. at 570.

C. Even if there had been a defect in the ABID System, surgical misuse of the ABID System was the sole cause of any alleged injuries.

Mr. Zeman does not allege that his injuries were the result of a defective device, but instead were the result of his surgeon misusing the ABID System causing a double dose of the study agent to be injected in the left side of his brain. “[O]ne cannot be held liable for negligent conduct unless it is causally related to injury of the plaintiff.” *Kent*, 437 Mass. at 320 (quoting *Wainwright v. Jackson*, 291 Mass. 100, 102 (1935)). Causation is “an essential element” of any negligence claim. *Glidden v. Maglio*, 430 Mass. 694, 696 (2000) (plaintiff failed to prove that defendant’s conduct caused his injuries); *Kent*, 437 Mass. at 321 (dismissing complaint where subsequent action by third party absolved the defendant of any liability as a matter of law).

Here, the Amended Complaint repeatedly acknowledges a superseding event: the defendant surgeon mistakenly placed both catheters in the left side of Mr. Zeman’s brain. Mr. Zeman is adamant that this act was the cause of a double dose and his injuries. *See, e.g.*,

Amended Complaint at ¶38 (“the two catheters were both placed in the left side of his brain delivering a double dose of the study agent only on the left side of the brain”); *id.* at ¶39 & Ex. B (CT scan shows “the right catheter was misplaced into the left STN”); *id.* at ¶57 (“Massachusetts General Hospital provided a limited number of records including the CT scan revealing that the right side catheter had mistakenly terminated in the left sub-thalamic nucleus where the left catheter had been placed”); *id.* at ¶83 (“Dr. Williams instead caused the left-side SNT to be infused with two doses of the study agent”). Mr. Zeman even claims that Dr. Williams “fail[ed] to use the ABID System properly,” by “failing to place the ABID right-side catheter in such a position that the study agent within such catheter would be infused into the right-side SNT.” *Id.* at ¶70c, 70j.

Thus according to the Amended Complaint, the cause of any injuries allegedly suffered by Mr. Zeman was the erroneous placement of both catheters on the left side of his brain. Incredibly, had there actually been a malfunction in the right-side catheter of the ABID System, Mr. Zeman may have received only one dose in the left-side of his brain, and any such defect likely would have *reduced* the supposed injuries allegedly caused by the placement of both catheters in one side of the brain. Thus, Mr. Zeman cannot prove that a hypothetical defect in the ABID System caused his alleged injuries.

III. Count XIII – Mr. Zeman’s Breach of Implied Warranty Claim Fails As Inapplicable Under His Alleged Facts.

Mr. Zeman also brings a breach of implied warranty claim against both Neurologix and Medtronic, alleging that the ABID System was “defective in design and/or manufacture,” in breach of the implied warranties of merchantable quality and fitness for a particular purpose. Amended Complaint at ¶¶149-50. This claim also fails.

A. A breach of implied warranty claim requires a sale or lease.

Neurologix sponsored the clinical trial to test the safety and effectiveness of its cutting edge gene therapy drug. Participation in the study was free for all participants. Neurologix neither sold its study drug or the ABID System used in conjunction with the study, nor placed them into commerce. Under Massachusetts law, a breach of warranty claim requires a sale or lease of a product. *Mason v. Gen. Motors Corp.*, 397 Mass. 183, 186 (1986) (dismissing wrongful death suit on behalf of decedent who test drove defendant's vehicle because "a sale, or a contract to sell, or a lease is necessary in order for a warranty of merchantability to be implied under Massachusetts law"). *See also* Morton F. Daller, *Product Liability Desk Reference, A Fifty-State Compendium* (2011 ed.), p. 383 ("Because Massachusetts' strict liability-analogue claims are based on the UCC's implied warranty of merchantability, such claims must be grounded on a sale or lease of new or used goods by a merchant."). Without such sale, Mr. Zeman's claim fails.

B. Even if there was such a thing as an implied warranty in a clinical study, Zeman's breach of warranty claim fails for three additional reasons.

1. The implied warranty of fitness for a particular purpose is not applicable.

The Amended Complaint fails to set forth any facts that support a claim of breach of the implied warranty of fitness for a particular purpose. This theory is plainly inapposite because Dr. Williams used the ABID System in order to perform the very surgical procedure for which the device was developed.

In *Stuto v. Corning Glass Works*, 1990 WL 105615 (D. Mass. July 23, 1990) (Wolf, J.), this Court dismissed a claim for breach of the implied warranty of fitness for a particular purpose for the very same reason. The Court aptly described fitness for a particular purpose as follows:

This warranty envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those

envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question. The warranty only applies when the seller has reason to know that the buyer will put the goods to a particular unusual use and is relying on the seller's skill to provide suitable wares. *Id.* at *3 (citations and quotations omitted).

This type of claim does not exist where, as here, the plaintiff intended to put the device to its customary use. *Id.* See also *Laspesa v. Arrow Int'l, Inc.*, 2009 WL 5217030, at *4 (D. Mass. Dec. 23, 2009) (finding for defendant on fitness for a particular purpose where the "doctors used Arrow's catheter for one of its most common purposes, the administration of an epidural sedative").

2. *Mr. Zeman has failed to state a claim of breach of implied warranty of merchantability for defective design.*

As discussed more fully above in Section II.A., legally Mr. Zeman's claim of defect in the design of the ABID system is fully preempted by federal regulations. The function of the clinical study is to test the safety and efficacy of the designed medical procedures and devices. Mr. Zeman's after-the-fact challenge of the clinical study's design and underlying medical device hinders the experimental purposes of the FDA regulations. Thus, Mr. Zeman's breach of warranty claim is preempted pursuant to federal law.

Factually, Mr. Zeman fails to state a claim for relief for at least three additional reasons. Under Massachusetts law, a claim based on design defect requires the plaintiff to prove the following elements: (1) the defendant designed a defective product; (2) the defendant's defective product was more likely than not the cause in fact of the injury; (3) the defendant's defective product was more likely than not the proximate cause of the injury; and (4) a safer design was feasible. *Haglund v. Phillip Morris, Inc.*, 2009 WL 3839004 (Mass. Super. Ct. Oct. 20, 2009). First, as described in Section II.B, *supra*, the Amended Complaint does not actually allege any defect in the ABID System. Second, as described in Section II.C, *supra*, any defect was not the

cause of Mr. Zeman's alleged injury. Finally, essential to any claim for design defect is the allegation of an alternative design. *See Laspesa*, 2009 WL 5217030, at *3; *Back v. Wickes Corp.*, 375 Mass. 633, 642 (1978). Here, Mr. Zeman makes no such allegation, and for good reasons: (a) there was no defect in the original design, and (b) an alternative design would not have been permissible without the FDA's further approval.

3. *Mr. Zeman has failed to state a claim of breach of implied warranty of merchantability for manufacturing defect.*

Mr. Zeman's allegation of manufacturing defect is similarly without merit. Simply put, Mr. Zeman makes no factual allegation to support this claim—there is no allegation, nor could there be, that the ABID System used on Mr. Zeman “deviate[d] in its construction or quality from specifications or planned output in a manner that renders it ‘unreasonably dangerous.’” *Laspesa*, 2009 WL 5217030, at *3 (citations omitted). As explained above, Mr. Zeman claims that “nothing in the medical records provided to Plaintiff Zeman corroborates the claim that the right catheter malfunctioned.” Amended Complaint at ¶55. He instead has placed the blame on the medical professional's alleged misuse of the ABID System. As a result, Mr. Zeman's legal conclusion of manufacturing defect is without any factual support and must be dismissed. *See Twombly*, 550 U.S. at 555.⁹

IV. Count XIV – Mrs. Zeman's Loss of Consortium Claim Fails Due to the Lack of an Underlying Tort.

Any claim for loss of consortium requires an underlying tort that caused the loss of society, companionship, or sexual availability. *Charron v. Amaral*, 451 Mass. 767, 769 (2008); *Sena v. Commonwealth*, 417 Mass. 250, 264 (1994). *See Schumaker v. C.R. Bard*, 1996 U.S.

⁹ Moreover, Mr. Zeman has made no showing that any manufacturing defect caused his alleged injuries. His complaint alleges on several occasions that the medical professional performing the study erred during surgery by placing both catheters on the same side of Mr. Zeman's brain. *See* Amended Complaint at ¶¶38, 39, 55, 57, 70j.

Dist. Lexis 822 (D. Mass. Jan. 3, 1996) (Wolf, J.) (without surviving claims of product liability, negligence, and warranty, the “derivative” loss of consortium claim was also dismissed). Where there is no underlying tort, no secondary layer of tort liability running to the benefit of the spouse can lie. Consequently, because Mr. Zeman fails to state a claim against Neurologix, his wife’s loss of consortium claim against the company also must fail.

CONCLUSION

For the foregoing reasons, the Court should grant Neurologix’s motion in its entirety, and enter final judgment dismissing it from plaintiff’s lawsuit without delay.

NEUROLOGIX, INC.

By its attorneys

/s/ Christopher H. Lindstrom
George A. Xixis (BBO# 663116)
gxixis@nutter.com
David L. Ferrera (BBO# 631183)
dferrera@nutter.com
Christopher H. Lindstrom (BBO# 657430)
clindstrom@nutter.com
Nutter, McClennen & Fish, LLP
Seaport West, 155 Seaport Blvd.
Boston, Massachusetts 02210
Telephone: (617) 439-2000
Facsimile: (617) 310-9698

Dated: May 27, 2011

CERTIFICATE OF SERVICE

I certify that, on May 27, 2011, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

/s/ Christopher H. Lindstrom
Christopher H. Lindstrom